DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 14, 2015

Covidien
Mr. Michael Koczocik
Product Specialist, Regulatory Affairs
60 Middletown Ave
North Haven, Connecticut 06473

Re: K143644
Trade/Device Name: Premium Surgiclip™; Endo Clip™; AcuClip™
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: FZP
Dated: August 4, 2015
Received: August 7, 2015

Dear Mr. Koczocik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
For Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

COVIDIEN

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143644

Device Name
Premium Surgiclip

Indications for Use *(Describe)*
The Premium Surgiclip™ clip applier has application in many types of surgical procedures to occlude vessels and other tubular structures and for vagotomy, sympathectomy and radiographic markings

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143644

Device Name

Endo Clip™

Indications for Use *(Describe)*

Endo Clip™ M, ML, L - The Endo Clip™ clip applier has application in endoscopic procedures to achieve occlusion of vessels and other tubular structures, and for radiographic markings.

Endo Clip™ 5mm - The Endo Clip™ clip applier has applications in endoscopic procedures to achieve occlusion of vessels and other tubular structures and for radiographic markings.

Endo Clip™ II - The Endo Clip™ II clip applier has application in many types of endoscopic procedures to achieve occlusion of vessels and other tubular structures and for radiographic markings.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

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Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143644

Device Name

AcuClip™

Indications for Use *(Describe)*

The instrument is primarily indicated for patients undergoing laparoscopic surgical procedures involving dissection and occlusion of blood vessels, ducts and other tubular structures. It can also be used to mark anatomical structures during surgery, and for radiographic marking.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary

This 510(k) summary of data used to demonstrate substantial equivalence is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR § 807.98

NAME:	COVIDIEN
ADDRESS:	60 Middletown Avenue North Haven, Connecticut 06473 USA
CONTACT PERSON:	Michael Koczocik Product Specialist, Regulatory Affairs
PHONE NUMBER:	(203) 492-6312
FAX NUMBER:	(203) 492-5029
DATE PREPARRED:	March 13, 2015
TRADE/PROPRIETARY NAME:	Premium Surgiclip™ Endo Clip™ AcuClip™
COMMON/USUAL NAME:	Surgical clip appliers with implantable clips
CLASSIFICATION NAME:	Implantable Clip per 21 CFR § 878.4300
PRODUCT CODE:	FZP
CLASSIFICATION PANEL NAME:	General and Plastic Surgery
FDA PANEL NUMBER:	79
DEVICE CLASS:	Pursuant to 21 CFR § 878.4300 implantable clips are Class II devices
PREDICATE DEVICE(S):	Premium Surgiclip™ III (K853650), (K142869) Endo Clip™ (K061288), (K883018) AcuClip™ (K920599)

INTENDED USE:

Premium Surgiclip™ (All models) The Premium Surgiclip™ clip applier has application in many types of surgical procedures to occlude vessels and other tubular structures and for vagotomy, sympathectomy and radiographic markings

Endo Clip™ M, ML, L The Endo Clip™ clip applier has application in endoscopic procedures to achieve occlusion of vessels and other tubular structures, and for radiographic markings

Endo Clip™ 5mm The Endo Clip™ clip applier has applications in endoscopic procedures to achieve occlusion of vessels and other tubular structures and for radiographic markings

Endo Clip™ II The Endo Clip™ II clip applier has application in many types of endoscopic procedures to achieve occlusion of vessels and other tubular structures and for radiographic markings

AcuClip™ The instrument is primarily indicated for patients undergoing laparoscopic surgical procedures involving dissection and occlusion of blood vessels, ducts and other tubular structures. It can also be used to mark anatomical structures during surgery, and for radiographic marking.

Device Descriptions

Reorder Codes: Premium Surgiclip™
134031 - Premium Surgiclip™ M-11.5
134044 - Premium Surgiclip™ M-9.75
134046 - Premium Surgiclip™ S-9.0
134048 - Premium Surgiclip™ L-13.0
134051 - Premium Surgiclip™ II M-9.75
134053 - Premium Surgiclip™ II M-11.5

Description of Premium Surgiclip™ Devices
The Premium Surgiclip™ clip applier consists of an applier shaft with attached handles and integrated cartridge containing 15 or 20 titanium clips. The clip applier jaw is placed around a vessel or other tubular structure. As the handles of the applier are brought together, the clip is closed around the vessel or structure. As the handles are released, a new clip is automatically loaded into the clip applier jaw.

Models available are:

Premium Surgiclip™ M – 11.5 and Premium Surgiclip™ II M-11.5 – medium sized clips with an 11.5 inch shaft

Premium Surgiclip™ M – 9.75 and Premium Surgiclip™ II M-9.75 – medium sized clips with an 9.75 inch shaft

Premium Surgiclip™ S-9.0 – small sized clips with an 9.0 inch shaft

Premium Surgiclip™ L-13.0 – large sized clips with an 13.0 inch shaft

Reorder Codes: Endo Clip™
176615 – Endo Clip™ ML
176619 – Endo Clip™ M
176625 – Endo Clip™ L

The Endo Clip™ clip applier contains 20 titanium clips in the ML and M sizes, and 15 titanium clips in the L size. They are designed for introduction and use through all appropriately sized Covidien™ trocar sleeves, or larger sized trocar sleeves with the use of a converter.

176620 – Endo Clip™ 5mm

The Endo Clip™ 5mm clip applier contains 12 titanium clips. The applier is designed for introduction and use through an appropriately sized Covidien™ trocar sleeve, or larger with the use of a converter. The overall length of the shaft is approximately 28 cm (11”).

176657 – Endo Clip™ II

The Endo Clip™ II clip applier contains 20 titanium clips. The appliers are designed for introduction and use through all appropriately sized Covidien™ trocar sleeves, or larger sized trocar sleeves with the use of a converter.

Reorder Codes: AcuClip™
OMS-A8 – AcuClip™

The AcuClip™ right angle clip applier is loaded for delivery of twenty (20) 8 mm titanium ligating clips. It is designed for introduction and use through all appropriate sized Covidien™ trocar sleeves or larger trocar sleeves with the use of a converter. The distal portion of the AcuClip™ right angle clip applier forms a hook that is placed around the vessel or other tissue structure to be occluded. The clips are advanced into the jaws by squeezing the handle approximately half-way. The clips are then closed by fully depressing the handle.

SUMMARY COMPARING THE TECHNOLOGICAL CHARACTERISTICS OF THE PROPOSED AND PREDICATE DEVICE(S)	The clip appliers are designed to occlude vessels and other tissue and tubular structures. The technological characteristics of the proposed devices remain the same as the 510(k) cleared predicate devices. (Premium Surgiclip™ III K853650, K142869),(EndoClip™ K883018 & EndoClip™ III K061288), & (Acuclip K920599)
MATERIALS:	All components of the Premium Surgiclip™ Endo Clip™, and AcuClip™ are comprised of materials which are in accordance with ISO 10993-1
PERFORMANCE DATA:	In-vitro and In-vivo performance testing were not conducted as a requirement of the labeling change to add a contraindication.

CONCLUSION:	The addition of the contraindication does not alter the performance of the devices.The Premium Surgiclip™, Endo Clip™, and AcuClip™ are determined to be substantially equivalent to predicate devices (Premium Surgiclip™ III) K142869),(EndoClip K061288), & (Acuclip K920599)